REMARKS

This amendment is in response to the Office Action dated 9/16/03, and is filed concurrently with a Request for Continued Examination (RCE) and a Petition for a 3-month Extension of Time. Entry of this Amendment and reconsideration of this application are respectfully requested.

Finding of new matter added to specification

In the Examiner's paragraph 6, the Examiner states that the definition of "temporal differences" to include a metric indicating a scalar of how good/bad, how much change (vector), or how strongly (acceleration) an action is happening is not supported by the original specification.

In response, the language (in the paragraph between page 7, line 21 and page 8, line 4) which added this definition to the specification has been cancelled.

Claim Rejections under 35 U.S.C. §112

Claims 1-19 and 21-23 were rejected under 35 U.S.C. §112, as failing to comply with the written description requirement.

Claims 1 and 19 have been extensively amended, such that they no longer rely on the definition of "temporal differences" which has been cancelled herein.

Claims 11-18 and 23 have been cancelled.

Having overcome the rejections of claims 1 and 19 under §112, the rejection under §112 of dependent claims 2-10 and 21-23 should also be overcome.

Claims 6-7 and 9-10 were rejected under §112 because the limitation "said composite image" lacked a proper antecedent basis.

The Examiner is correct. The terms "derived image" and

"composite image" were inadvertently used interchangeably in the claims. The claims have now been amended to consistently use the term "composite" image, thereby curing the antecedent basis problems of claims 6-7 and 9-10.

Claim Rejections under 35 U.S.C. §102

Claims 1 and 9-10 were rejected as anticipated by a patent to Yanagita et al.

Claims 1 and 9-10 have been amended to better clarify their differences with respect to Yanagita. Claim 1 is directed to a method of visually documenting historical changes in biological tissue. As amended, the claimed method comprises:

(a) obtaining a first image of a region of tissue;

(b) obtaining pathological feature data for the region of tissue;

(c) obtaining a second image of the region of tissue using a first level of resolution;

(d) digitally storing the first and second images as digitized first and second images;

(e) spatially adjusting at least one of the first and second digitized images to spatially register the images so that corresponding features in both images are mapped to corresponding positions;

(f) correlating the pathological feature data with the second image to define a historical region-of-interest (ROI) in the second image;

(g) rescanning the defined ROI using a second level of resolution higher than the first level of resolution to produce a third image;

(h) spatially adjusting at least one of the historical and rescanned ROI images to spatially register the ROI images so that corresponding features in both ROI images are mapped to corresponding positions; and

(i) creating from the historical and rescanned ROI images a composite image which visually emphasizes temporal differences between the ROI images, thereby visually emphasizing historical changes between the historical and rescanned ROI images.

The amendments made to claim 1 are fully supported by the specification. See, e.g., page 5, line 5 to page 7, line 24, and FIGs. 2a and 2b.

The amended claim thus requires the obtaining of three images of a region of tissue, with each image having unique characteristics. After obtaining a first image of a region of tissue for a given patient, a second image is obtained using a first, relatively low resolution level. The claim requires that pathological feature data be obtained and used to define a "historical" ROI in the second image. Then, the defined ROI is rescanned using a high resolution level - thereby producing a "rescanned ROI image". The claim further requires that the first and second images, and the historical and rescanned ROI images, be spatially registered. Finally, a composite image (alternately referred to in the specification as a "difference image") is created from the historical and rescanned ROI images which visually emphasizes temporal differences between the ROI images, thereby visually emphasizing historical changes between the historical and rescanned ROI images.

This is considerably different from the much simpler method disclosed in Yanagita. As shown in his FIG. 2 and described at column 8, lines 13-36, Yanagita performs basic subtraction processing between sequentially-acquired images. Yanagita is directed to a display system ("Image Displaying Apparatus"), that can switch between temporally sequenced images that have been stored in memory, as well as between subtraction images.

However, Yanagita fails to show a number of the essential elements of the amended claim 1. For example, Yanagita says nothing about:

- obtaining pathological feature data for the region of tissue;
- obtaining a low resolution image followed by a high resolution image of a defined ROI;
- the use of pathological feature data to define a "historical" ROI in the low resolution image;
- performing a high resolution rescan of the defined ROI to produce a rescanned ROI image;
- creating a composite image from the historical and rescanned ROI images which visually emphasizes temporal differences between the ROI images, thereby visually emphasizing historical changes between the historical and rescanned ROI images.

all of which are required by the amended claim 1.

The amended claim clarifies the low resolution followed by high resolution imaging process. Defining or registering two images involves translation (x,y,z), rotation, and scaling efforts. If done exclusively using high resolution images, then an estimate of the number of steps required to accomplish the registration would be:

- Translation: maximum number of pixels in either x or y
- Rotation: total resolution in x divided by total resolution in y (tangential value of x and y) divided by y
- Scale: maximum number of pixels in either x or y

If the applicants' "low resolution" imaging has half the resolution of the high resolution imaging, then half of the registration steps are eliminated. Thus, a significant number of incremental steps are eliminated using the lo-res/hi-res process of the amended claim 1. The process recited in the amended claim also allows for manual intervention by the user to define

specific regions of interest, and thereby improve the correlation step process.

In sum, there is a vast difference between Yanagita's approach and that of the applicants, with the applicants utilizing a much more complex and efficient analysis method which yields substantially more information than does the Yanagita apparatus.

A claim is anticipated when every one of its elements is disclosed in a single prior art reference. As has been shown above, Yanagita fails to disclose most of the elements recited in the amended claim 1. Thus, Yanagita cannot and does not anticipate the amended claim 1, which is therefore allowable over Yanagita.

The amended claim 1 is the parent of claims 9-10, which are therefore allowable along with claim 1.

It should be noted that claim 10 is also allowable on independent grounds. Claim 10 requires that the composite image of claim 1 visually emphasize temporal image differences by representing various regions of the composite image in synthetic colors, based upon temporal image differences between the historical and rescanned ROI images. This is not disclosed in the cited art. Neither Yanagita, nor any of the other cited art, discloses the use of historical and rescanned ROI images, the creation of a composite image from such images, or the use of synthetic colors to emphasize temporal image differences - all of which are required by claim 10. Therefore, claim 10 is allowable on this independent basis.

Claim Rejections under 35 U.S.C. §103

Claims 2-3 and 5-6 were rejected as obvious over Yanagita in view of a patent to Kawachi et al.

The amended claim 1 is the parent of claims 2-3 and 5-6, which are therefore allowable along with claim 1.

However, the applicants assert that several of these claims are allowable on independent grounds. Claim 3, for example, which has been amended to better clarify its differences with respect to the cited art, requires that the coordinate transformation specified in claim 2 be determined by:

(a) applying coordinate transformations of scale, position and rotation to one of said first and second digitized images, to obtain a plurality of corresponding adjusted images;

(b) cross-correlating said adjusted images with one of said first and second digitized images, to produce a correlation output; and

(c) selecting a coordinate transformation which produces at least a defined correlation output from its corresponding adjusted image.

The Examiner asserts that the elements of claim 3 are disclosed in Kawachi. They are not. Kawachi discusses a simple means of comparing an image taken by an image processing device and comparing it with a model image. As described in Kawachi at the lines (col. 7, lines 7-13) cited by the Examiner, a measurement region image 27r is searched by a region designating image 27q, until the correlation value of both images exceeds a reference value. This bears virtually no resemblance to the detailed process specified in claim 3. Kawachi neither discloses or suggests applying coordinate transformations of scale, position and rotation to obtain a plurality of corresponding adjusted images.

Kawachi is a self-focusing system in a factory or autonomous scanning environment. The projected image (27) (model image) is projected onto the object (1) of interest to provide a fixed and known focal length that is directly controlled by the lens (21). The object can then be moved away or toward the scanner (2) to bring it into focus and scale. The parameters defined by the objects, lines and arrows, for the projected image help to translate the region of interest (ROI) within the object. There is no similarity between the Kawachi process and that recited in the amended claim 3. Kawachi is not concerned with the content of the model image, whereas the applicants are concerned with subtle translations within the plurality of images - each plurality having a unit translation with respect to each other. Whereas Kawachi's model image is a constant.

Claim 7 was rejected as obvious over Yanagita and Kawachi in combination with a patent to Wang.

The amended claim 1 is the parent of claim 7, which is therefore allowable along with claim 1.

Claim 8 was rejected as obvious over Yanagita and Kawachi in combination with a patent to Mitchell.

The amended claim 1 is the parent of claim 8, which is therefore allowable along with claim 1. Please note that claim 8 has been amended to conform to the amended language of claim 1.

It should also be noted that claim 8 requires that at least one of the historical and rescanned ROI images be a three-dimensional image; none of the cited art discloses or suggests 3-D imaging. The amended claim 8 is thus also allowable on this independent basis.

Claims 4, 19, 21 and 23 were rejected over Yanagita and

Kawachi in combination with a patent to Trezza.

The amended claim 1 is the parent of claim 4, which is therefore allowable along with claim 1.

Claim 19 is an independent claim directed to a system for enhancing imagery of bodily tissues by relating earlier and later images. The claim has been amended in a fashion similar to that of claim 1, to better clarify its distinctions with respect to the cited art. As amended, claim 19 comprises:

- an image processor, programmed to:

(a) receive a first image of a region of tissue;

(b) obtain pathological feature data for the region of tissue;

(c) obtain a second image of the region of tissue using a first level of resolution;

(d) register the first and second images by controlling an optical correlator to find a position of correlation between the first and second images;

(e) correlate the pathological feature data with the second image to define a historical region-of-interest (ROI) in the second image;

(f) rescan the defined ROI using a second level of resolution higher than the first level of resolution to obtain a third image;

(g) register the historical and rescanned ROI images by controlling an optical correlator to find a position of correlation between the historical and rescanned ROI images;

(h) derive a composite image from the historical and rescanned ROI images;

(i) compute temporal differences between the historical and rescanned ROI images; and

(j) emphasize the temporal differences in the composite image; and

- an optical correlator coupled to the image processor and arranged to perform the correlations.

Thus, as in claim 1, the system of claim 19 requires the image processor to obtain three images of a region of tissue. After obtaining a first image of a region of tissue for a given patient, a second image is obtained using a relatively low resolution level. The claim requires that pathological feature data be obtained and used to define a "historical" ROI in the second image. Then, the defined ROI is rescanned using a high resolution level - thereby producing a "rescanned ROI image". The claim further requires that the first and second images, and the historical and rescanned ROI images, be spatially registered. Finally, a composite image is created from the historical and rescanned ROI images which visually emphasizes temporal differences between the ROI images, thereby visually emphasizing historical changes between the historical and rescanned ROI images. The correlations are required to be performed using an optical correlator.

As noted above, this is considerably different from the much simpler system disclosed in Yanagita. Yanagita is a display system which performs basic subtraction processing between sequentially-acquired images. Yanagita fails to disclose a number of the essential elements of the amended claim 19. For example, Yanagita says nothing about:

- obtaining pathological feature data for the region of tissue;

- obtaining a second image of the region of tissue using a first level of resolution;

- correlating the pathological feature data with the second image to define a historical region-of-interest (ROI) in the second image;

- rescanning the defined ROI using a second level of resolution higher than the first level of resolution to obtain a third image;

- registering the historical and rescanned ROI images by controlling an optical correlator to find a position of correlation between the historical and rescanned ROI images;

- deriving a composite image from the historical and rescanned ROI images;

- computing temporal differences between the historical and rescanned ROI images; and

- emphasizing the temporal differences in the composite image; - using an optical correlator coupled to the image processor which is arranged to perform the correlations.

all of which are required by the amended claim 19.

In sum, there are substantial differences between Yanagita's system and that recited in the applicants' claim 19, with the applicants utilizing a much more complex and sophisticated system method which yields substantially more information than does the Yanagita apparatus.

The patents to Kawachi and Wang do nothing to cure the deficiencies of Yanagita. Neither discusses or suggests obtaining pathological feature data for the region of tissue, obtaining a low resolution image followed by a high resolution image of a defined ROI, the use of pathological feature data to

define a "historical" ROI in the low resolution image, performing a high resolution rescan of the defined ROI to produce a rescanned ROI image, or creating a composite image from the historical and rescanned ROI images which visually emphasizes temporal differences between the ROI images, thereby visually emphasizing historical changes between the historical and rescanned ROI images.

As such, even if combined as suggested, the cited art fails to disclose most of the elements of the amended claim 19. Thus, the amended claim 19 would not have been obvious at the time the invention was made in view of Yanagita, Kawachi and Wang. Claim 19 is thus allowable over the cited art.

The amended claim 19 is the parent of claim 21, which is therefore allowable along with claim 19.

Claim 23 has been cancelled.

Claim 22 was rejected as obvious over a combination of Yanagita, Kawachi, Trezza and Wang.

The amended claim 19 is the parent of claim 22, which is therefore allowable along with claim 19.

Claims 11-18 were rejected as obvious over various combinations of references.

Claims 11-18 have been cancelled.

New claims

New claims 24-28 have been added:

Claims 24-26 are directed to various method of obtaining

the pathological feature data recited in the amended claim 1. Support for these claims is found in the specification at page 5, line 16 through page 6, line 2.

Claim 27 requires that the second image of the amended claim 1 be obtained using ultrasonic imaging. Support for this limitation is found in the specification at page 6, lines 3-7.

Claim 28 requires that both the historical and rescanned ROIs are three-dimensional volume regions which are aligned by registration in three dimensions. Support for this limitation is found in the specification at page 7, lines 18-20.

No new matter has been added.

All of the claims presently in the application are believed to be in proper form for allowance. A Notice of Allowance is respectfully requested.

Respectfully submitted,

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